Common Or Contract Delivery Vehicles

The company selects common or contract carriers that provide adequate security to guard against in-transit losses.

Further, the company takes precautions to assure that shipping containers do no indicate contents are controlled substances so as to guard against storage or in-transit losses.

When distributing controlled substances through agents, the company provides and requires adequate security to guard against theft and diversion while the substances are being stored or handled by the agent or agents.

Delivery Vehicle Security Rules (Form #17) are provided to contract carriers for distribution to drivers. Rules are reviewed and signed by drivers.

Depots/Line Haul Shipments

The use of cross-dockings and line hauls means vehicles with larger quantities of controlled substances and other merchandise and increased vulnerability to theft and/or diversion during the run from the distribution center to the depot. To protect against internal theft that may go undetected until the orders get to the customer level, ensure that vehicle contents are checked and signatures obtained upon pickup and delivery and that line haul vehicles are secured with a numbered seal that must be cut off or broken upon arrival at the depot.

Seal Construction Specifications

Durability A seal must be strong enough to prevent accidental breakage during normal use.

Design The design must be sufficiently complex to make unauthorized manufacture of a replacement seal difficult.

Tamperproof The seal should provide readily visible evidence of tampering and prevent reconstruction after the seal is closed; that is, a seal needs construction to make simulated locking difficult.

Individually Identifiable Identification is best accomplished by embossing serial numbers and owner identification on each seal.

Seal Accountability Procedures

Record of Application Seal numbers are entered or written on transportation documents such as bills of lading and manifests.

Time of Application Trailers must be sealed immediately after the loading is completed. Roll-up-type doors must be sealed at the loading dock. Swing-out doors must be sealed immediately after the unit is far enough away to close the doors.

Verification Seal examination and verification at every stop such as docks and transfer points. Multiple stops require new seals. Persons receiving sealed shipments must examine the seal and record the number on appropriate documentation, such as a log.

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Retain broken seals until it is determined whether there are any discrepancies. If there are none, destroy the seal. If discrepancies are found, retain the seal pending investigation.

U.S. Postal Mailing And Delivery

DEA regulations applicable to the use of the U.S. postal services state: "Controlled substances including Schedule II may be sent in any quantity by registered mail, return receipt requested, from one DEA registrant to another DEA registrant. The packaging must be in plain outer containers and give no indication of the contents."

Will Call Orders

Verification calls are to be made to the person in charge of the licensed premises for whom the order is intended and the name and description of the person picking up the order and the items included in the order are obtained.

When the individual arrives to pick up the order, the shipping supervisor checks the individual's name by asking for the driver's license and comparing the description of that provided by the person in charge of the licensed premises.

The person picking up the orders signs a **Will Call Log (Form #18)** that is dated and initialed by the shipping supervisor. The driver's license number and the person's name are then recorded both on the packing slip and the will call log.

Note: Many wholesalers have discontinued will call orders for controlled substances to avoid this high risk diversion exposure.

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PERSONNEL

Additional information is located in the Employee Handbook.

Pre-Employment Screening

Cardinal Health requires all prospective employees to sign a **Pre-Employment Waiver (Form #19)** consent to a physical examination, which includes a drug test, and to an investigation made of their background and fitness for the position for which they have applied.

Cardinal Health reserves the right to immediately dismiss any employee when the results of the physical examination or drug test show signs of substance abuse and/or the background investigation reveals a history of criminal activity or other information which would deem the employee unfit for the position.

Any information associated with the physical examination or background investigation will be gathered and held in the strictest confidence by Cardinal Health in accordance with all applicable laws.

It is recommended that employment should not commence until the results of the physical examination and drug test are received and reviewed by the appropriate management personnel of Cardinal Health.

Upon commencement of employment, the new employee will complete a **Post-Employment Security Data Information Sheet (Form #20).** The completed sheet is sent to the Corporate Compliance Department to conduct a criminal record check.

Controlled Substance Requirements

When an employee is promoted or transferred it may be necessary to review his/her background, depending on the nature of the transfer or promotion. Anyone allowed unsupervised access to the cage or vault in order to perform job functions must complete the **Test for Distribution Center Employees Handling Controlled Substances (Appendix B)** as well as the **Post-Employment Security Data Information Sheet.** The test and form must then be submitted to the Corporate Compliance Department. The department will grade the test and each individual must pass with a score no lower than 88%. If an employee does not pass the test, he/she must re-take the test at a later date and must obtain a passing score. The employee should be advised that prior to his or her working inside the controlled substance area an in-depth background investigation will be performed. The results of this background check along with the individuals test score will be shared with division management. The background check should be performed prior to the distribution center manager assigning the employee to the controlled substance area.

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Security Rules

The following list of security rules has been developed to promote a safe and secure working environment for all employees and to assure compliance with United States Drug Enforcement Administration Security Regulations.

- Possessing, dispensing, or using a controlled substance without a medical prescription or reporting to work or working under the influence of alcohol or a controlled substance without a medical prescription is strictly prohibited. If an employee requires medication which may affect their performance, they should notify their supervisor immediately. DEA regulations regarding this should be posted in the facility **(Exhibit D).**

- Defacing Company property or willful negligence resulting in damage due to mishandling of merchandise or destructive abuse of machines or other Company equipment is prohibited.

- Falsifying an employment application, time card, production record, or other documents for yourself, customers, or another employee is prohibited.

- Protection of Company property is a responsibility all employees must share. Any employee discovering theft, loss, or malicious damage has an obligation to report the incident immediately to his supervisor.

- Fighting or instigating a fight with an employee, customer, or supplier while on Company property is strictly prohibited. No permanent personnel action will be taken until there is a complete investigation by Management.

- Tampering with or breaching Company security systems or policies is prohibited.

- Theft or unauthorized removal or use of Company or another employee's property is prohibited.

- Possession of firearms or illegal weapons on Company property is prohibited.

- Employees must use their own card entry access card, and access cards should not be loaned to other employees. Lost access cards should be reported to Management immediately.

- Employees must use authorized employee entrance when entering and exiting the building and must use their own access card when doing so.

- Entrance and exits to the facility are to be closed at all times, unless being used for the purpose they are designed.

- All bags, boxes, lunch boxes, containers, etc., are subject to inspection when exiting the facility. Signs to this affect should be posted throughout the distribution center **(Exhibit E).** Random periodic inspections could serve as a deterrent to internal theft.

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- Locker assignments and locks will be issued by Cardinal Health. Personal locks are not allowed. Locks will be subject to inspection by Management at their discretion.

- Visitor's entering the distribution center should be asked to sign in on a **Visitor's Log (Form #21),** indicating their name, who they represent, time in, time out, and who they are visiting at the distribution center. Each visitor should wear a badge and must be escorted during their stay.

- Warehouse access is limited to employees who have full-time assignments that require their presence in the warehouse.

- Coats and pocketbooks are not allowed in the warehouse.

- Employees are to adhere to the posted access list for the cage and vault area.

- A **Miscellaneous Security Log (Form #22)** should be used to document any minor security-related incidents that occur but do not need to be explained in detail.

Security rules should be distributed to all employees and a signature obtained to document receipt.

Violence Prevention Procedures

The sign entitled **Violence Prevention Procedures (Exhibit G)** should be posted in conspicuous locations throughout the distribution center. These procedures should be reviewed with distribution center employees on a routine, periodic basis. It is paramount that **all** employees know exactly what to do in case they are confronted with a possible violent situation. Additional copies of these signs may be obtained through the Corporate Compliance Department.

Driver Security Rules

Drivers are required to adhere to the following security rules:

- Test all vehicle locks each day and immediately report defects to a supervisor.
- Keep all merchandise in the rear of the truck. Leave nothing in the cab.
- Secure the truck when making a delivery. Roll up all windows, lock all doors and take the keys with you.
- Do not stop for stranded motorists. This could be a setup for a hijack. If you feel it is necessary to call for assistance, do so at your next stop.

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- Make it a habit to check your rear view mirror to see if you are being followed. If you suspect that you are being followed, obtain a description of the vehicle, the license number and the occupants. Proceed to the local police station; if this is not possible, proceed to your next stop and call the local police or the office.
- If you break down, stay with your truck. Leave only to call for assistance.
- Avoid areas where the threat of theft is high (such as back doors and alleys). If something appears suspicious, do not stop.
- In the event of a robbery:
  a. Offer no resistance.
  b. Stay calm.
  c. Be observant.

Driver security rules should be distributed to all drivers and a signature obtained to document receipt.

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INSPECTIONS OVERVIEW

Overview

The Comprehensive Drug Abuse Prevention and Control Act of 1970 (the Controlled Substances Act") authorizes the Drug Enforcement Administration (DEA) to enforce provisions of the act as they apply to registered handlers of controlled substances. The stated DEA goal is *"to significantly reduce the availability of licitly produced drugs used for illicit purposes in the United States."*

The act establishes a comprehensive system to control the manufacture and distribution of controlled substances necessary for legitimate medical needs. Since the controlled substances in question include some of the most potent drugs known to man, the incentive to divert these drugs into the illicit market is great. Drug related deaths and injury statistics indicate that legally produced controlled substances account for a large percentage of drugs associated with drug abuse injuries reported by hospital emergency rooms. In fact, 15 of the top 20 controlled substances reported in hospital emergency room mentions were pharmaceuticals legally available in the United States market.

The DEA Diversion Control Program is responsible for implementing and maintaining controls over the distribution of legally produced controlled substances and for investigating diversion of these substances into the illicit market. The Diversion Control Program prevents, detects, and investigates the diversion of controlled substances from legitimate channels, while at the same time ensuring an adequate and uninterrupted supply of controlled substances required to meet legitimate needs. To achieve this goal, DEA's diversion program uses programs designed to maximize the effect of criminal, civil and regulatory investigations and controls intended to limit the availability of diverted substances.

The diversion control program operates through: periodic investigations to ensure that record keeping, reporting, and security requirements are being met; targeted investigations (for violative registrants); preregistration investigations; an organized system of drug destruction; manufacturing quotas; and drug scheduling (collection of abuse and diversion information). Periodic inspections are conducted as circumstances may require, based in part on the registrant's history of compliance and maintenance of effective controls to guard against the diversion of controlled substances.

These activities are designed to meet DEA's responsibilities under the Controlled Substances Act and to prevent the diversion of controlled substances from legitimate distribution channels. When violations are discovered, appropriate action (administrative, civil or criminal) will be considered.

As we move further into the 1990s, the pharmaceutical industry is facing an increasingly active enforcement and regulatory climate.

DEA registrants must be aware of this climate, and ensure that they are in full compliance with DEA requirements or take immediate corrective action before DEA investigates their facility.

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Notice of Inspection

Cardinal Health recognizes the fact that federal and state regulatory agencies have explicit authority to inspect our premises and records.

Upon notice of a federal or state regulatory inspection, contact the Corporate Compliance Department immediately and advise to the nature of the visit, names of the officials and the agency they represent. The Department can be of assistance in helping to verify an individual's identification if the need arises.

Full cooperation must be given to the inspecting authorities. However, only persons authorized by division management may answer questions posed by the regulatory inspector. Inspections should be monitored closely by qualified Cardinal personnel, and a daily detailed written record in the inspection must be prepared.

Upon arrival of the investigators at the registered location, the manager, his/her designated alternate and the individual who has overall responsibility for controlled substances should meet with the investigators as soon as possible, review their credentials (a picture of the person on an official ID Card)and accept the DEA Notice of Inspection. Inspector(s) should be asked to sign the Visitor's Log and given a Visitor Badge to be worn at all times. A discussion should then be held regarding the purpose and extent of the investigation and the desire of management for a close-out discussion at the completion of the investigation. **(21 CFR 1316.05)**

If you are not sure that the individual requesting entry is a bona fide city, state, or federal official do not allow them to enter the distribution center. Request information as to whom they report (their immediate supervisor) and how (telephone number) you can verify their identification.

Note:Receptionist should not admit inspector(s) into facility or accept their credentials.

Authority of the DEA Investigator

21 USC 880 and **21 CFR 1316.03** allow DEA investigators to enter a registered location (controlled premises) upon stating their purpose and presenting credentials and a written notice of inspection or, if warranted, an administrative inspection warrant for the purpose of:

- Inspecting and copying records, reports and other documents required to be kept or made;
- Inspecting, within reasonable limits and in a reasonable manner, all pertinent equipment, finished and unfinished controlled substances and other substances or materials, containers, and labeling found at the controlled premises relating to the Controlled Substances Act;
- Conducting a physical inventory of all controlled substances on the premises;
- Collecting samples of controlled substances pursuant to DEA Form 84; and
- Checking records and information regarding the distribution and receipt of controlled substances by the registrant.

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Exclusion From Inspection

Unless consented to in writing by the registrant, no inspection authorized by 21 USC 880 and the implementing regulations should extend to:

- Financial data;
- Sales/receipt data other than shipping and receiving data; or
- Pricing data.

Entry to Premises

DEA officials will conduct the investigation. The officials have the right to enter the registered premises and conduct the investigation at reasonable times in a reasonable manner once they state their purpose, present their credentials and written notice of their inspection authority (DEA Form 82) to their responsible registrant official, and receive informed consent or present an administration inspection warrant.

An administration inspection warrant is not required if informed consent is obtained from the registrant. Whenever possible, the informed consent should consist of a written statement (DEA Form 82 with addendum— language found in Section 1316.08) signed by the registrant.

Investigation

An individual (preferably a responsible officer or employee) who is familiar with the DEA record keeping and reporting requirements and security in place at the facility always should accompany and monitor the investigators.

This individual should be prepared to:

- Immediately notify the personnel responsible for the various areas to be involved in the investigation prior to the investigators visiting the areas;
- Explain the operation/type of security, record keeping and reporting systems/procedures maintained;
- Assist the investigators;
- Verify the accuracy of the information the investigators obtain from inventories, sales and purchases documents and make a list of the records reviewed;
- Obtain copies for and retain copies of any documents the investigators request;
- Assure that information volunteered is clearly beneficial to the wholesaler;
- Assure no misrepresentations are given to the investigators;
- Note any suggestions or criticisms expressed by the investigators. Any violations discovered in this manner should be corrected immediately and documented; and
- Complete a daily detailed written record of inspection that includes the following:
  - any questions raised by the inspector,

- any questions raised by the monitor,
- any requests made by the inspector,
- what the inspector was shown,
- a list of any records viewed or copied by the inspector,
- items inventoried and verification of the inspector's counts,
- any suggestions of criticisms expressed by the inspectors,
- complete a **DEA Inspection Report (Form #23)** and forward to Corporate Compliance Department.

Note: The registrant using this report and statements made by the investigator should reconstruct the investigation to verify any violations or, as is possible, reveal no violations.

All personnel are instructed not to read, acknowledge in any way, or sign any affidavit presented to any Company employee by an investigator.

Discussion with Management (Close Out)

This phase will be used by DEA to reinforce the findings by acquiring the registrant's acceptance of the cited violations and willingness to correct them, or the registrant's challenge of the findings by non-acceptance of the violations. Explain that Cardinal Health, Inc. employs a Director of Compliance and inquire if the results of the inspection warrants his presence at the exit interview. If yes, contact the Director of Compliance immediately. If the DEA intends to take further action, the registrant may or may not be informed of what courses of action are possible. The registrant will not be informed of the specific action to be recommended.

*Note: DEA is **not required** to conduct a closing discussion at the completion of the investigation. If not initiated by the investigator, the registrant should request a closing discussion at the convenience of the investigator. If this fails, it is suggested that a request be made in writing to the investigator's supervisor, expressing the desire to meet and discuss the findings and any corrective action that may be required.*

If a closing interview is held, the investigator may advise the registrant of any violative conditions. If the registrants cannot obtain a closing discussion, the report prepared by the employee(s) assigned to accompany the investigator during the investigation should be utilized to reconstruct the investigation and findings.

Once aware of any violations, the registrant should take the following initiatives in seeking and implementing corrective actions:

- Reconstruct the investigation and findings, using the same documents, facility review utilized by the investigators and the registrant's internal report.
- Take appropriate action to correct any violations or problems uncovered during the DEA investigation; and
- Convey to DEA the corrective action taken, what steps the registrant has taken to prevent future problems and inquire what further action the registrant should take.

It is suggested that if a registrant's investigation disagrees with the DEA investigation, they should contact DEA immediately and request a meeting to discuss the findings.

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DISTRIBUTOR ACCOUNTABILITY INVESTIGATIONS PROCEDURES

An investigation is divided into four phases: preparation, on-site, follow-up and past history. The information sought by the DEA during each phase is outlined below.

Preparation

Prior to inspecting a facility, the registrant files at the respective DEA location are reviewed; i.e., review of ARCOS reports, review of registration categories and schedules, etc.

On-Site Investigation

Initial Phase

The initial phase involves initial discussion, presentation of investigator credentials and notice of inspection (if a warrant is used, the registrant should consider the need for an attorney). The credentials and notice will be presented to that person who has managerial responsibility for operating the firm. The investigator should state the purpose and indicate the scope of the investigation.

Management at this time should request that the investigators advise them of any violations discovered during the investigation so that corrective action can be taken immediately. Management should state that they desire a closing discussion at the completion of the investigation.

Background Information

The DEA investigators will want to know the:

- Names, addresses, date of birth and social security numbers of corporate officers and/or owners of the registrant and identification of individuals responsible for record keeping and security;
- Number of employees and appropriate registration (federal, state and local); and
- Percentage of business dedicated to controlled substances.

They also will want to review reporting procedures regarding thefts, losses or destruction of controlled substances.

A completed copy of the **DEA On-site Background Information Package (Form #28)** can provide the DEA Inspectors with pertinent company information.

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Closing Inventory

The closing inventory is usually taken before or after business hours, so that no adjustments for transactions outside the accountability period are necessary. An accurate inventory is necessary and advantageous. All shipping, receiving and return areas, as well as other areas where controlled substances might be stored, should be checked.

A responsible employee of the registrant should verify the accuracy of the inventory and make a copy for the registrant's records.

Initial Inventory

An actual inventory taken by the registrant, an inventory from a previous DEA investigation or a computer inventory printout may be utilized if the registrant will attest to its accuracy.

Regardless of the inventory used, the required biennial inventory will be reviewed.

Receiving Records

Order forms will serve as the primary record of documenting the receipt of Schedule II controlled substances. They also will be reviewed for accuracy.

The power of attorney will be reviewed.

ARCOS reports and purchase invoices will be reviewed to verify accuracy of the order form transactions for Schedule II controlled substances and Schedule III narcotic controlled substances.

Receiving records which record supplier's name, address, and DEA number; name of controlled substance; strength; quantity received; and date of receipt for Schedule III through Schedule V will be reviewed. These records must be kept in a readily retrievable manner. The registrant will be required to attest to the accuracy of the records.

Sales Records

Order forms will serve as the primary record documenting the sale of Schedule II controlled substances. They also will be reviewed for accuracy.

Registration of customers will be verified.

A sampling of ARCOS records and customer sales records for Schedule II controlled substances and Schedule III narcotic controlled substances will be reviewed to verify shipments.

The quantity of Schedule III through Schedule V controlled substances distributed may be determined from a number of different types of records. The primary record is the distributor's sales invoice.

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Sales will include all dispositions from inventory, including documented and reported thefts, returns and destructions.

Credits and Returns

A review of credit memoranda will be made to determine that there was physical movement of controlled substances or credit.

Returned controlled substances will be inspected to verify that there is documentation showing returns, disposition by destruction or return to inventory.

Note: If the registrant has another record keeping system, such as the computerized Selected Item Audit Report which contains all required information and attests to its accuracy, these records may and should be used.

ARCOS

Reports will be verified by comparing them to other purchase and sales records.

Accountability

The initial inventory is combined with all receipts (including returns) of controlled substances and compared to the closing inventory plus sales, destructions, returns, reported thefts or losses accounted for by the registrant from its records.

Security

This evaluation will include:

- Review of location, crime classification, building construction, access restrictions and storage areas, including size and type of physical security systems in place;
- Evaluation of alarm systems and test;
- Review of security and procedures employed in shipping and receiving areas, picking areas, and packaging areas;
- Review of procedures for determining proper registration of customers;
- Review of frequency of alarm checks and procedures for key control, after hours entry, badge system and lock changing; and
- A review of the registrant's system for monitoring unusual and excessive orders.

Discussion with Management

This will be used to reinforce the findings by acquiring the registrant's acceptance of the cited violations and willingness to correct them, or the registrant's challenge of the findings by nonacceptance of the violations. If DEA's intention is to take further action,

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the registrant may be informed of courses of action possible, but not the specific action to be recommended.

*Note: DEA is **not required** to conduct a closing discussion at the completion of the investigation. In this case, the registrant should request a closing discussion at the convenience of the investigator. If the request is not successful, it is suggested that the registrant send a written request to the investigator's supervisor, expressing the desire for a meeting to discuss any findings and corrective action which may be required.*

Follow-Up Investigation

After the on-site portion of the investigation is completed, a verification of purchases and sales most likely will be performed. The extent of the verification will depend upon the nature of the investigation and discrepancies found. In addition, DEA may conduct file checks on all persons who are interviewed during the investigation.

History of Violations

The registrant's history if violations will be taken into consideration by DEA in determining the type of action to be levied against the registrant.

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VIOLATIONS

The DEA will take action against a registrant in all instances where an investigation reveals violations of the Controlled Substance Act and the implementing regulations. The **Table of Offenses and Penalties (Exhibit H)** summarizes these violations.

Administrative Actions

Revocation of Non-Practitioner Registration or Application Denial

DEA registration or application may be revoked, suspended or denied if at least one of the following conditions is present:

- The application for registration has been materially falsified;
- The registrant (owner, officer, controlling stockholder) has been convicted of a drug related felony;
- The registration is inconsistent with the public interest. Factors to be considered in determining public interest include the following:
  1. Maintenance of effective controls against diversion,
  2. Compliance with applicable state and local law,
  3. Prior conviction record relating to controlled substances,
  4. Registrant's violative history,
  5. Such other factors as may be relevant to and consistent with the public health and safety; or
- The registrant's state license or registration to handle controlled substances has been suspended, revoked or denied.

"No Automatic Renewal" of Registration

To prevent renewal of the registrant's registration, the DEA will place an administrative code on the registration.

This procedure is usually utilized to suspend approval of the renewal application when the investigation shows that the registrant has failed to maintain adequate controls against diversion and grounds for denial exist.

The registrant is authorized to continue operating on a day-to-day basis until final action is taken (voluntary surrender, denial of renewal application or removal of the administrative code).

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Letter of Admonition

The letter of admonition advises the registrant of the violations found and documents these violations in written form. This allows for voluntary, corrective actions by the registrant and makes the violations a matter of record should the same violations be encountered at a later date.

Administrative Hearing

A hearing will be held when the severity of the violations and the registrant's attitude toward them render the letter of admonition ineffective. An administrative hearing provides DEA and the registrant with the opportunity to explain their respective views on the violations and to discuss the necessary corrective actions.

Order to Show Cause

An order to show cause may be issued to a registrant for denial, revocation or suspension of a DEA registration for one of the following factors:

- The application for registration has been materially falsified;
- The registrant has been convicted of a drug related felony;
- The registration is inconsistent with the public interest. Factors to be considered in determining public interest include the following:
  1. Maintenance of effective controls against diversion,
  2. Compliance with applicable state and local law,
  3. Prior conviction record relating to controlled substances,
  4. Registrant's violative history,
  5. Such other factors as may be relevant to and consistent with the public health and safety; or
- The registrant's state license or registration to handle con-trolled substances has been suspended, revoked or denied.

During a show cause hearing, the registrant has the opportunity to explain why the registration should not be suspended or revoked.

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Civil or Criminal Prosecution

The use of civil or criminal prosecution will be determined by the severity of the violations found during the investigation and discussions with DEA management and the assistant U.S. attorney.

The determination between civil and criminal prosecution is made based upon the registrant and/or person knowingly or intentionally committing the violation(s).

Civil penalties are assessed at $10,000 per violation.

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Guide to Handling ARCOS Transactions

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Guide To Handling ARCOS Transactions

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GUIDE TO HANDLING ARCOS TRANSACTIONS

Introduction

The Automation of Reports and Consolidated Orders System (ARCOS) was developed by the DEA to report inventories of selected controlled substances and increases and decreases to these inventories. The selected controlled substances are Class II and III narcotics.

Transactions can be reported electronically via tape or diskette, or manually using ARCOS Form 333. In most divisions, a majority of the ARCOS records are created automatically during the receiving, invoicing and crediting processes. Other records must be created by manually entering the data into the ARCOS Maintenance Menu.

A report of all ARCOS transactions generated by the system is available for review. Depending on the system, this may be daily or monthly. Prior to submission to ARCOS, erroneous transactions can be changed or corrected using the ARCOS Maintenance Menu.

Distributors are required to take an annual inventory of each reportable controlled substance on December 31st and file it with ARCOS no later then January 15th of the following year. Increases and decreases in the inventory of each reportable controlled substance must be reported on a monthly basis and filed with ARCOS no later than the 15th of the month following the end of the reporting period.

For automated reporters, a tape of these transactions is sent to ARCOS, with a hardcopy report maintained at the division for two years. This report is useful when researching errors identified by ARCOS as it contains additional information, including item number and description, invoice number and customer or vendor number. For manual reporters, hand-written transactions are submitted to ARCOS on Form 333. One copy of the form is maintained at the division for two years.

ARCOS 'reads' the tape and generates a report entitled "ARCOS Daily Transactions Processing Error Report." The report will either acknowledge that no errors were found, or will list the transaction records in error, with the error code, description of the error and a correction number. Corrections must be made and the transactions resubmitted. Error reports should be maintained at the division for two years.

All media submitted to ARCOS should have a barcode label attached. Submissions should be made as described below:

ARCOS reports sents via commercial carrier such as Federal Express (FedEx), United Parcel Service (UPS) should be sent to:

DEA Headquarters
Attn: ARCOS Unit
2401 Jefferson-Davis Highway
Alexandria, VA 22301

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ARCOS reports sent via the U.S. Postal Service must use the following address:

Drug Enforcement Administration
ARCOS Unit
P.O. Box 27273
Washington, D.C. 20038-7273

Inquiries can be made to the ARCOS Unit at (202) 307-8600.

What to do before sending a report to ARCOS

The Distrack system has a daily report of ARCOS transactions, while the HP generates the report at month-end. Each system has the ability to make changes, additions and deletions prior to the submission of the transactions to ARCOS. Instructions can be found in the ARCOS Maintenance Section.

In the review process, look for

- DEA numbers that do not fit the typical format (2 letters followed by 7 numbers),
- blank numbers that do not fit the typical format (9 digit number),
- items that are not ARCOS reportable,
- quantities that appear to be excessive or out of the ordinary, and
- inventory adjustments.

Keep in mind that the only transactions that need to be reported to DEA are those that document an actual transfer of product. Records created by inventory adjustments when the product is moved from the live inventory to the morgue inventory do not represent a transfer of product and should be deleted. Credit and rebills for contract/chargeback purposes and dropship billings are two more examples of financial transactions that do not represent the actual transfer of product.

If changes need to be made to an Associate's DEA registration number, the modification should also be made in the Customer or Vendor Master File so that future transactions do not contain the same error.

ARCOS reportable items that are documented as lost-in-transit or stolen on DEA Form 106 or as destroyed on DEA Form 41, need to be reported as transactions to ARCOS. Since forms to the DEA are submitted manually, ARCOS records are not generated by the system and need to be created.

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